DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP - 8 2009

Re: Entereg
Patent Nos. 5,250,542 and 5,434,171
Docket Nos.: FDA-2009-E-0073
And FDA-2009-E-0015

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 5,250,542 and 5,434,171 filed by Eli Lilly and Company, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for Entereg (alvimopan), the human drug product claimed by the patents.

The total length of the regulatory review period for Entereg (alvimopan) is 5,305 days. Of this time, 3,879 days occurred during the testing phase and 1,426 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: November 12, 1993.

   The applicant claims November 11, 1993, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 12, 1993, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: June 25, 2004.

   FDA has verified the applicant's claim that the new drug application (NDA) 21-775 was submitted on June 25, 2004.

3. The date the application was approved: May 20, 2008.

   FDA has verified the applicant's claim that NDA 21-775 was approved on May 20, 2008.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Donald J. Bird
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